



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,862	09/08/2000	Keith Henry Stockman Campbell	112800.301	2555

21269 7590 12/19/2001

PEPPER HAMILTON
600 FOURTEENTH STREET NW
WASHINGTON, DC 20005

EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,862

Applicant(s)

STOCKMAN CAMPBELL ET AL.

Examiner

D. Crouch

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/803,165.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 5.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The term "genetically modified", in claims 39 and 44, is interpreted as containing an exogenous DNA sequence or transgenic (see specification, page 5, line 30 to page 6, line 2 and page 7, lines 4-14).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35-38 and 40-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are not distinguished over a mammalian embryo or mammal found in nature. The claims are to products produced by a particular process. However, neither the mammalian embryo nor the mammal is altered by the process so that the "hand of man" is present. Therefore, the claimed mammalian embryos and mammals are not seen as a new manufacture or composition of matter as required by 35 U.S.C. 101.

Claims 39 and 44 have intentionally been omitted as they encompass transgenic nonhuman mammalian embryos and transgenic nonhuman mammals, which would be altered by the hand of man. (See definition of "genetically modified" above.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35,38,39,40,43 and 44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 39 and 44 state that the "cell has been genetically modified prior to nuclear transfer." However, it is not clear if in this instance the resultant mammalian

Art Unit: 1632

embryo (claim 39) or mammal (44) has the same set of chromosomes as a nonhuman, non-embryonic mammal of the same species. The claims are being examined as if the cell being transferred is from a transgenic nonhuman mammal as this is the contemplation in the specification.

Claims 38 and 43 state "wherein the cell is abstracted *ex vivo*." The meaning of the term is not clear and there is no definition in the specification. For examination purposes, the term is taken to mean that the cells are isolated from multicellular embryos.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,057,420 issued October 15, 1991 (Massey).

Massey teaches bovine embryos isolated from cows that have been artificially inseminated (col. 3, lines 18-31). Bovine embryos encompassed by the present claims and made by a particular process of the claims do not have a property that distinguishes them from those bovine embryos taught by Massey. That the claimed embryos have the same set of chromosomes as a nonhuman, non-embryonic mammal does not provide a distinguishing feature to the resultant embryo, as the source of the embryo's chromosomes does not affect the embryo. Thus, Massey clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d

Art Unit: 1632

1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 40-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by The Science of Providing Milk for Man, Campbell and Marshall, McGraw Hill Book Co., New York, 1975, pages 48, 49, and 51-56.

At pages 48,49 and 51-56, Campbell and Marshall teach several different bovines that existed prior to applicant's invention. A bovine produced by the claimed methods would not be patentably distinct from any one of the bovines of Campbell and Marshall as the method does not provide a patentably distinguishing feature to the claimed mammal. That the claimed mammals have the same set of chromosomes as a nonhuman, non-embryonic mammal does not provide a distinguishing feature to the resultant mammal, as the source of the mammal's chromosomes does not affect the mammal. Thus, Campbell and Marshall clearly anticipate the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 34-38 and 40-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

Sims teaches the production of bovines and bovine embryos by nuclear transfer, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2,

Art Unit: 1632

parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). The source of the donor nucleus, be it bovine inner cell mass cell or a non-embryonic cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims is patentable distinct from those of Sims et al. Indeed, the bovine embryo and bovine of Sims contains the same set of chromosomes as a non-embryonic bovine of the same species, that is the same chromosomes as the donor bovine. Thus, Sims clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 34,39,40 and 44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 95/17500 published 29 June 1995 (Stice).

Stice teaches transgenic nonhuman mammalian embryos and transgenic nonhuman mammals produced by nuclear transfer where the nuclear donor is an embryonic cell comprising a genetic modification (page 33, lines 14-24). The source of the donor nucleus, be it a genetically modified nonhuman embryonic cell as Stice teaches or a genetically modified non-embryonic, nonhuman mammalian cell as claimed, does not provide a patentable distinction on the resulting genetically modified nonhuman embryo or genetically modified nonhuman mammal. The source of the donor nucleus does not alter the embryo or mammal such that the embryo or mammal encompassed by applicant's claims is patentable

distinct from those of Stice et al. Further, Sims teaches that the cells are cultured *in vitro* and are abstracted *ex vivo* (page 6144, 1, 8-15). Thus, Sims clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D., Acting SPE of AU 1632 whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

D.C.
December 17, 2001